30 September 2010

Comments on the *"Draft Implementing technical guidance - List of fields for result-related information to be submitted to the 'EudraCT' clinical trials database, and to be made public, in accordance with Article 57(2) of Regulation (EC) No 726/2004 and Article 41 of Regulation (EC) No 1901/2006 and their implementing guidelines 2008/C168/02 and 2009/C28/01"*

Comments from:

Name of organisation or individual
H. Lundbeck A/S

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	Lundbeck welcomes the publication of this draft implementing technical guidance and appreciates the opportunity of providing comments. Our comments are expressed below for consideration: **Scope of the studies to be made available:** It is not explicitly stated which trials are to be included, e.g. phase 1 studies, compounds no longer in development, observational studies, etc. **Review process and timing of the submitted data:** There is no description throughout the draft document with regard to the review step of the data submitted. It states that results will be made public within 5 days of submission of a valid dataset. Today the review process on the US clinicaltrials.gov can	

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	take up to many months. However, the sponsor would have fullfilled the requirements by submitting the data within the timeframe required by the US legislation. The draft document would benefit from more clarification with this regard, e.g. will the review process be similar to its US counterpart and if different, what would be the difference? **Relationship with marketing status:** Also, there are no comments about marketing approval. It has been stated before that results will be posted regardless of whether the compound is approved or not. If this still is the case how is the European Commission going to separate this information from other results. Will there be a search separating for approved and non-approved drugs? **Discussion and interpretation of results:** With regards to including 'Discussion and interpretation' in the results to be published, it is not clear how this can	

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	fit versus medical journal publication. Posting results on clinical trial registries/databases is not generally regarded as (pre-)publication. However, adding a *'discussion and interpretation'* section in the data submitted might be regarded as conflicting. Some journals will only consider manuscripts for publication if less than 500 words have been placed on clinicaltrials.gov (See e.g., Neurology (http://www.neurology.org/misc/auth2.dtl), which states in their instructions to authors that: *'The Food and Drug Administration Amendment Acts of 2007 require mandatory results reporting for clinical trials. (See http://prsinfo.clinicaltrials.gov/fdaaa.html.) Neurology, following the ICMJE policy, will not consider results posted in the same clinical trials registry in which the primary registration resides to be previous publication if the results are presented in the form of a brief, structured (<500 words) abstract or table. The authors should alert the Editor in the cover letter at submission that the review of the manuscript should be accelerated if possible.')*	

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	A 'Discussion and Interpretation' will seriously jeopardise the acceptance of the primary manuscript from the clinical trial.	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome
Section A P3		The statement "Final date on which data was collected" implies that these fields are to be filled in after the study is completed. This comment is also relevant for other fields, e.g. P8, P15. Since the information is protocol-related the statement may not be appropriate.	
Section A P10		'Wait list control' is not mentioned for psychotherapy.	
Section A P13		Please clarify whether only controlled studies are required to be registered or whether observational studies are also part of the scope.	
Section A P15		Please clarify the information to be provided in case of a non-Medline-indexed publication.	
Section A P16		Please clarify what "other relevant location" means. Are links to a company public clinical trial result portal accepted?	
Section B R1		This field should not involve a named individual (they may no longer work at the company)	
Section B R3 and B R5		This implies a named individual. Please specify that it could be	

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		a "function" within the company.	
Section B R10		Please clarify whether all the points listed have to be addressed, e.g. pain and distress are not always relevant. However "criteria for which a patient must be withdrawn" are specified and used in clinical trials. Do these criteria cover the required information for this field?	
Section B R12		A limit of 350 characters may be unrealistic – e.g., for a 5-arm study with run-in, taper-up, treatment, taper-down and follow-up periods. Please consider increasing the number of authorised characters.	
Section B R15		Please clarify whether this fields applies when the IMP is used as add-on therapy. Would this involve describing the medicinal product on top of which the IMP is used?	
Section B R17		Please clarify which periods of a study are required. Are only periods in which efficacy is assessed required to be mentioned?	
Section B R23		Please define what would be the baseline in the case of an extension study.	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome
Section B R27		"Withdrawal of consent" is not mentioned as an option. Please consider including it. Also please clarify whether this is a total number for all treatment arms per period.	
Section B R30		It might be more appropriate to use 'dataset' instead of 'population' in the section title. Also, please define what is meant by the terms: ITT, Safety population, FAS, even though the terms are commonly used.	
Section B R33		Please clarify what 'integers' means. Are numbers required per treatment arm?	
Section B R34		Please clarify what 'completed' means in the case of a relapse prevention study. Does it include relapsed patients?	
Section B R41		Please clarify what 'customised gender' means. Also please clarify how can race and ethnicity be defined and whether both are required. clinicaltrials.gov supplies a reference document for defining race and ethnicity. Is there something equivalent with EudraCT?	

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Section B R45		The 'standard error of the mean' (SE or SEM) is not mentioned. Please consider including it as well.	
Section B R92		It is standard practice within the pharmaceutical industry to list Serious Adverse Events (SAEs) separately and to include them in the Adverse Event (AE) incidence table to give an accurate picture of safety and tolerability. Please consider this approach for displaying AE tables.	
Section B R98		Please define TESS and the difference with TEAE. It seems to be a 'typo' error. Isn't it rather, 'DESS' (discontinuation emergent signs and symptoms)? If so, please correct. If otherwise please clarify.	

Please add more rows if needed.